GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2171
ANSWERED ON:06.08.2010
CLINICAL TRIALS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether foreign Pharmaceutical Companies are using Indian patients for clinical trials on a large scale in the country;

(b) if so, the details thereof;

(c) the names of such Foreign Pharmaceutical companies;

(d) whether these companies have taken approval of the Government for this;

(e) if not, the action taken/being taken by the Government on them; and

(f) the number of persons who died during clinical trials so far?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b) Clinical trails are permitted in the country as per Rule 122DA, 122DAA, 122DB 122E and Schedule Y of Drugs & Cosmetic Rules. Number of clinical trials permitted as part of global clinical trials and local clinical trial for marketing authorization during last 3 years is as follows:

Year	Number of global Clinical trial permitted	Number of local clinical trial permitted
2007	259	142
2008	246	275
2009	258	195
2010 (up to June)	117	134

(c) There are large number of pharmaceutical companies & Clinical Research Organizations (CRO) who seek permission from Central Drugs Standard Control Organisation (CDSCO) to conduct clinical trial in the country, which include Glaxosmithkline, Johnson & Johnson, Sanofiaventis , MSD, Eli Lilly, Novartis, Bristol Myers Sqibb, Bayer Healthcare, Astra Zeneca, Pfizer etc. and Clinical Research Organizations (CRO) like Quintiles, ICON, GVK BIO Siro Clinpharm, Parexel, PRA International PPD, Covance, Omnicare, Kendle etc.

(d) & (e) No company can initiate any Clinical trial of new drug without prior approval from CDSCO, Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of India.

(f) Death may occur during clinical trials due to various reasons. These could be disease related deaths like cancer etc or administration to critical or terminally ill patients or side effects of unrelated cause. Such deaths are investigated for causal relationship by investigator and by medical experts of sponsor. The information collated have revealed that there were 132 deaths in the year 2007, 288 deaths in the year 2008, 637 deaths in the year 2009 and 462 deaths up to June, in the year 2010.